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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/921,533	09/02/1997	PERTTI TORMALA	2880/27	9610

26646 7590 03/22/2002

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EXAMINER
CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/921,533	Applicant(s) TORMALA ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- Th MAILING DATE of this communication app ars on th cov r she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of extension of time and request for RCE under 37 CFR 1.114 is acknowledged.

Claim Rejections - 35 USC § 112

Claim 1 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claims recite that the resorbable polymeric reinforcing component as a large-scale reinforcing element is mixed with the resorbable polymeric matrix component. However, this limitation is a new matter because the instant specification only describes mixing the polymeric matrix with bioceramic or bioglass reinforcing element and not with the large-scale polymeric reinforcing element. The ceramic reinforcing component and the polymeric matrix are then combined with the polymeric reinforcing element by melt mixing by coating or by using solvent as an intermediate to preform the material. (see page 7, lines 11-16). This is also supported by the examples described on pages 8-10, where the mixture of poly (L, D-lactide) and hydroxyapatite is reinforced with poly (L-lactide) fibers. Accordingly, the claim limitation is a new matter.

In this regard, please refer to applicants remarks submitted with preliminary amendment B, dated 1-31-00 (page 3 last paragraph and page 4first paragraph), where applicants state that the bioceramic material is mixed with the matrix and the same is then reinforced with polymeric reinforcing material.

Applicants mentioned in the instant **Remarks** section that the claim 2 has the same requirements as the instant claims 1 and 16. However, examiner disagrees with this statement because, claim 2 requires mixing the first polymer and bioceramic to form a mixture, selecting second polymer in a fiber form, placing it in a desired formation and combining the matrix and bioceramic mixture with reinforcing polymer to form a second mixture. This is distinctly different from preparing a mixture of matrix and polymeric reinforcing component and a mixture of bioceramic component and matrix.

Claim Rejections - 35 U.S.C. § 102

1. Claims 1-6 and 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent No. 5084051 to Tormala et al (hereafter '051).

'051 teaches surgical biocomposite material suitable for bone surgical applications comprising a polymeric reinforcing element and bioceramic element, wherein the polymeric reinforcing element could be a mixture of polymers or polymer and porous or non porous bioceramic material (abstract, lines bridging cols. 1 and 2; col. 3, lines 14-53; col. 4, lines 19-68, col. 5-6, col. 8, lines 61-68, col. 9-10). The reinforcing polymer is in the form of reinforcing fibers and the resulting composite has good mechanical strength and integrity and is easy to handle. '051 teaches the various methods of manufacturing the composite as claimed in the instant invention and the addition of additives that facilitate bone growth and /or antibiotics in the composite material. In particular, the description of the biocomposite of Fig.1a shows that a plate like composite is formed of a bioceramic and a polymer, which is reinforced with a fabric of fibers. Thus, the description of biocomposite meets the instant biocomposite material. Also

please refer to the new matter rejection. Further, examiner notes that in the instant case, both the matrix and reinforcing polymer could be the same material such as poly-lactide. '051 also teach that the second material component is made of polymeric material such as poly-lactide. Accordingly, the second component of '051 meets the claim requirement of matrix and reinforcing polymer.

Claim Rejections - 35 U.S.C. § 103

2. Claims 1-8 and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 5,084,051 to Tormala et al (hereafter '051).

'051 discussed above does not teach the claimed diameter of the reinforcing elements. However, '051 teach using different fibers, such as short, felt, non-woven fibers etc., (col. 8, lines 62-68 and also examples). '051 teaches the reinforcing elements to giver the required strength to the biocomposite, while at the same time allowing for maximum in growth of bone tissue (col. 7). Therefore, it is the position of the examiner that optimizing the parameters such as diameter or thickness of the fibers of reinforcing polymer as well as the size of the bioceramic particles is well within the scope of ordinary skill in the art, such that the composite allows for the in growth of the bone and fibers impart good mechanical strength to the composite. Further, '051 suggest using powders of bioceramics in the manufacture of biocomposites such that the biocomposite material that is not too ductile or too tough can be achieved.

3. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 5,084,051 to Tormala et al (hereafter '051) as applied to claims 1-8 and 11-22 above, and further in view of Bonfield et al.

Tormala discussed above does not teach the volume fraction of bioceramic as claimed in the instant invention. Bonfield et al teaches bone composites containing hydroxyapatite and polyethylene composites of 0.3-to 0.5 volume fraction, which imparts fracture toughness to the composite. Accordingly, it would have been obvious for one of a skilled artisan to machine the bone composites having a volume fraction because Bonfield teaches that between the above volume fractions the composites possess increased toughness and strength of the composite and have comparable mechanical properties with that of the bone.

4. Applicant's arguments filed 2-14-02 have been fully considered but they are not persuasive.

Applicants argue that none of the cited references when viewed alone or in combination, neither disclose nor suggest the instant invention, which requires a matrix polymeric component be mixed with a polymeric reinforcing element. However, as explained above the new limitation is not supported by the specification. See the new matter rejection above.

Tormala et al, US patent 5,084,051 ('051) teaches a combination of bioceramic component and a resorbable element, which includes a reinforcing element, to provide toughness and strength (col. 7, lines 40-55). Further, as required by instant claim 3, '051 teaches reinforcing component in the form of fibers (col. 8, lines 62-67). Finally, '051 teaches that the material component is manufactured from polymers, copolymers or ceramic material and/ or their

mixtures or alternatively, the resorbable polymer can be mixed with additives such as ceramic powders. (Claim 1 and col. 6, lines 22-40). Further, '051 teaches the same materials that constitute resorbable polymers and the ceramic components. Thus, '051 teaches a mixture of resorbable polymer and a ceramic component, as that claimed in the instant invention.

With respect to the teachings of Bonfield et al, applicants urge that the reference merely discloses volume fraction, but does not teach present claims. However, this argument is not persuasive because, Bonfield teaches hydroxyapatite reinforced composite materials and their role in increasing the bone toughness, which is the same field of endeavor as that of Tormala ('051). Accordingly, it is the position of the examiner that it would have been obvious for a skilled artisan at the time of instant invention to prepare bone composites having a suitable volume fraction, which increases the toughness and strength of the composite and thus has comparable mechanical properties with that of the bone. This is a case of prima facie obviousness.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lakshmi S. Channavajjala
Examiner
Art Unit 1615

March 19, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600